IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALLERGAN SALES, LLC and ALLERGAN, INC. Plaintiffs, v. SANDOZ, INC. and ALCON LABORATORIES, INC. Defendants.	Civil Action No. 2:17-cv-10129 WHW-CLW ***Electronically Filed*** **REDACTED**

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS DEFENDANTS' INEQUITABLE CONDUCT AND ANTITRUST COUNTERCLAIMS AND TO STRIKE DEFENDANTS' TENTH AFFIRMATIVE DEFENSE, OR ALTERNATIVELY TO BIFURCATE AND STAY DEFENDANTS' ANTITRUST COUNTERCLAIMS

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I. INTRODUCTION

In two cases tried to final judgment and affirmed on appeal over the course of nine years, Allergan's Combigan® inventions have been held valid over all the art asserted by Sandoz. In each of those cases, each of the four presiding courts also found, on a voluminous record, that Allergan had demonstrated that Combigan® had both unexpected efficacy and safety over the prior art. As the Federal Circuit succinctly stated in its most recent pronouncement on the inventions now before this Court: "Those efficacy [and safety] limitations are not disclosed by any prior art reference in the record." *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 994 (Fed. Cir. Dec. 22, 2017).

Yet now, after all this water under the bridge, Sandoz appeals to this Court's equitable powers to permit Sandoz to re-litigate these holdings and findings under the guise of a pernicious claim of fraud, the so-called "atomic bomb" of patent law, inequitable conduct. *Therasense, Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc). This Court should reject Sandoz's efforts. In its papers, Sandoz does not dispute that it has ***never*** before argued that any of the Combigan® patents were unenforceable for inequitable conduct, despite having the opportunity to do so. Nor does it dispute that its allegations require proving misconduct that occurred during the prosecution of patents that Allergan and Sandoz have already litigated to finality. And it does not dispute that it was aware of all the information in its pleadings in the prior cases.

Given these admissions, the Court should dismiss Sandoz's counterclaims because they were, or require proof of, compulsory counterclaims to the earlier litigations and because they are simply not plausible. While Sandoz claims it has a right to pursue these allegations at this point in time because it "never before had an opportunity" to assert counterclaims of unenforceability, and that Allergan's alleged omissions and misrepresentations "had not yet

happened," these statements are simply incorrect. (Dkt. 148 at 14, 16.) Both conflict with Sandoz's allegations as to when the supposed misconduct transpired—in most cases, a decade or more ago—and with Sandoz's theory of infectious inequitable conduct, which ***necessarily depends on*** Sandoz showing inequitable conduct for the already-litigated patents.

Tellingly, Sandoz avoids responding to Allergan's arguments on the merits, arguing instead that it is not precluded from making an inequitable conduct claim directed at the patents-in-suit here. But that is not what Sandoz is doing—under its theory of infectious inequitable conduct, its attack on the patents-in-suit is that they are infected by inequitable conduct from the ***earlier patents***—patents on which Sandoz is precluded from making inequitable conduct claims. And it has no real answer to the fact that four courts have found against it on the key points at issue—validity and unexpected results—other than to suggest that this Court may ignore those findings. Sandoz similarly does not even address how Allergan's repeated successes in these prior could litigations could somehow amount to antitrust violations. Instead, Sandoz hides in the sheer volume of its counterclaims to allege that its pleadings must be sufficient. But volume does not equate to adequate pleading. That is especially the case when the vast majority of Sandoz's allegations misstate the documents and facts of the case. The Court is not required to accept those misstatements as true even in the context of a motion to dismiss.

The maxim "he who seeks equity must do equity" is apropos here. It is the height of inequity to allege fraud after nearly ten years of silence, when memories are no longer fresh, witnesses no longer available, and evidence has become stale. Respectfully, this Court should dismiss Sandoz's inequitable conduct and antitrust counterclaims and strike defendants' tenth affirmative defense, or in the alternative, bifurcate and stay Sandoz's antitrust counterclaims.

II. FURTHER STATEMENT REGARDING SANDOZ'S ALLEGATIONS

A. Sandoz Distorts Allergan's Positions Regarding the Alleged Inequitable

Conduct

Rather than responding to the substance of Allergan's arguments, Sandoz instead responds to its own misstatements of Allergan's positions. One striking example is Sandoz's claim that "Allergan does not dispute that its attorneys acted unreasonably in comparing the results of the claimed 'invention' … to brimonidine TID…" (*Id.* at 29.) That is not true and Sandoz knows it. In section IV.B.2.a. of its Opening Brief, Allergan explained in detail that Sandoz's allegations related to Allergan's identification of the closest prior art during prosecution are meritless. That explanation included that the district court in Texas in the 2009-2013 litigation expressly ***agreed*** with the arguments as to the closest prior art that Allergan made to the examiner. (Dkt. 112 at 26-28.) As described below, Sandoz makes similar misstatements of Allergan's positions regarding many of its other allegations, for example, Dr. Schiffman's declaration (Dkt. 148 at 24), Dr. Duh's report (*id.* at 27), FDA Medical Reviews (*id.* at 31), and results of the 12T study (*id.* at 31). Rather than address Allergan's arguments, Sandoz pretends they do not exist, or wrongly claims that Allergan does not dispute them, even considering the present procedural posture. To be clear, Allergan will demonstrate why Sandoz's allegations are wrong should the need arise. (*See e.g.*, Dkt. 112 at 1-2, 12-15.) We address below a few of the most egregious of Sandoz's rampant mischaracterizations.

B. The Court Need Not Accept as True Sandoz's Unsupported Conclusions and Unwarranted Inferences

While the Court must accept all factual allegations in Sandoz's counterclaims as true at this stage of the case, the Court need ***not*** accept unsupported conclusions, unwarranted inferences or legal conclusions couched as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678-679 (2009); *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007). As demonstrated previously and again below, Sandoz's

allegations of inequitable conduct hinge on unsupported conclusions or unwarranted inferences, and not the facts on which Sandoz purports to rely.

1. Sandoz Makes Unwarranted Inferences Regarding Dr. Schiffman's Declaration

The Court need not accept Sandoz's allegation that "Dr. Schiffman's declaration was false and wrongfully failed to disclose Dr. Schiffman's employment at Allergan," (Dkt. 148 at 24), because the very documents Sandoz relies upon for its allegations show that neither statement is true. The Schiffman declaration did not contain false information, and Allergan disclosed to the PTO that Dr. Schiffman was an Allergan employee.

The Schiffman declaration presents the results of one of Allergan's clinical studies on Combigan®, the 19T study, to the PTO. (*See* Dkt. 148-3, Ex. 27 at 78-80.) In contrast to Sandoz's assertion, the declaration does not independently analyze the data from that study. Rather, Dr. Schiffman reports "[t]he percentage of patients in the Combination [i.e., Combigan®] group experiencing adverse events of the nervous system (0.0%)." (*Id.* at 78-79.) Review of the table attached to Dr. Schiffman's declaration indicates the percentage of patients experiencing adverse events with Combination treatment in the 19T study was, as the declaration states, 0.0%. (*Id.* at 80.) Dr. Schiffman's statement was true then and is true today.

That other data may differ from the results of 19T study does not render Dr. Schiffman's verbatim reporting of the 19T data false. Nor did Allergan "hide" such differing data. Indeed, the patent specification discloses data from the 13T study, which shows that patients taking Combigan® experienced some somnolence, the primary nervous system side effect upon which Sandoz relies. (*See e.g.*, Dkt. 148-2, Ex. 5 at 7:36.) Moreover, to the extent other clinical trial data showed some nervous system side effects, Allergan submitted that data to the PTO and specifically referred back to Dr. Schiffman's declaration, explaining why the results presented

there were still unexpected. (Walsh Decl., Ex. A at AGN_COMBI0141565-66.) As to Dr. Schiffman's employment, Allergan corrected that omission in the next office action response, more than a year before the Examiner allowed the patent, informing her that Allergan "overlooked mentioning in the previous action that the expert who signed the rule 132 affidavit is an employee of the assignee." (*Id.*, Ex. B at AGN_COM00000066.) The Court should not accept Sandoz's unwarranted inferences about the Schiffman declaration.

2. Sandoz Advances Unsupported Inferences Regarding the 12T Study

Similarly, the Court need not accept Sandoz's unwarranted inferences regarding the 12T study. Contrary to Sandoz's arguments, the data from the 12T and 13T studies do not show that the 12T study was "less favorable for Allergan's arguments" as Sandoz alleges. (Dkt. 148 at 6.) Instead, the studies were consistent with one another—in both the 12T and 13T studies, for each of the claimed side effects at both three and twelve months, the Combigan® group experienced lower rates of side effects than the brimonidine group, with one exception at the three month time point that resolved by twelve months. (*See, e.g.*, Walsh Decl., Exs. C-F.)

Sandoz's additional assertion that the 12T study "showed that Combigan had a higher incidence of nervous-system side effects (like somnolence) than did brimonidine TID" is also untrue. (Dkt. 148 at 12.) [redacted] Sandoz's incorrect statement to the contrary should be rejected.

FDA's analysis of the 12T and 13T study results further highlights Sandoz's mischaracterization of the 13T data as superior to the 12T data. The FDA Medical Review,

which was submitted during the prosecution of the '453, '801 and '802 patents and is relied upon heavily by Sandoz for its inequitable conduct arguments, states that there were "no significant differences between the 3 month and 12 months results of studies 012 and 013." (Dkt. 148-3, Ex. 25 at 40.) The Court should not simply accept Sandoz's distortion of the facts regarding the 12T and 13T studies.

3. Sandoz Draws Unwarranted Inferences from FDA Statements

The Court also need not accept as true, for the purposes of considering Allergan's motion to dismiss, Sandoz's assertion that FDA criticized Allergan's clinical trials, or its implication that Allergan's clinical data were unreliable. (*See* Dkt. 148 at 3, 7-8, 10, 12, 25, 31.)

The FDA statements cited by Sandoz are not criticisms of the underlying clinical data, but rather statements as to whether the data satisfactorily demonstrated the safety and efficacy of Combigan® for the purposes of regulatory approval. As Sandoz itself previously argued (before the Courts upheld the validity of the Combigan® patents), FDA approval "requirements are distinct from patentability." (Walsh Decl., Ex. J at 47-48); *In re Anthony*, 414 F.2d 1383, 1395 (C.C.P.A. 1969) ("approval by the FDA 'is not a prerequisite' for the patenting of a new drug"); *Scott v. Finney*, 34 F.3d 1058, 1063-64 (Fed. Cir. 1994). Sandoz's contention that these statements would have been material to the patentability of the Combigan® patents is unfounded in fact and in law.

4. Sandoz's Allegation that the 507T Study Was Withheld Is Wrong

Sandoz's allegation that "Dr. Johnson withheld that the 507T study showed Combigan had a significantly higher incidence of somnolence than did concomitant brimonidine BID and timolol BID" is similarly belied by the facts. (Dkt. 148 at 12.) Not only did Dr. Johnson submit a published article about that study to the Patent Office, which contains the very data Sandoz

alleges was withheld, he commented on that article to the Examiner and acknowledged the data it contains. (Walsh Decl., Ex. A at AGN_COM00000037.) The Court need not accept Sandoz's allegations based on the supposed withholding of a study that was not, in fact, withheld.

5. Sandoz's Representation of Dr. Duh's Conclusion Is Wrong

Sandoz falsely alleges that one of Allergan's litigation experts submitted a report contradicting the fact that Combigan® is as effective as brimonidine TID. [redacted] The Court need not accept any allegations about Dr. Duh's report that conflict with the report itself, as well as with four court decisions, including two from Courts that reviewed the report, finding that Combigan® is as effective as brimonidine TID.

6. Sandoz Draws Unsupported Conclusions from Alphagan® Prior Art

In reliance on a report on Alphagan®, Sandoz further asserts that Allergan knew there "were significantly fewer side-effects with the BID regimen" than the TID regimen. (Dkt. 148 at 31.) Sandoz's characterization of the data is wrong—the report on which it relies concludes "[n]o significant differences in any safety parameters were observed between the two treatment regimens,"—the opposite of Sandoz's characterization. (Dkt. 148-2, Ex 18 at

[1] All emphasis in quotations is added unless otherwise noted.

AGN_COMBI0676355.) Arguing both sides of the coin, Sandoz then asserts that Allergan published that there "were no clinical differences between brimonidine TID and BID," – contradicting its own allegation described above. (Dkt. 148 at 31.) Putting aside that Sandoz has taken this statement wildly out of context—a matter it is well aware of because it raised (and lost) this very argument in the first trial, *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d. 974, 996-97 n.9 (E.D. Tex. Aug. 22, 2011)—as soon as Sandoz raised this matter, Allergan disclosed the very abstract that contained that statement to the PTO. (Dkt. 148-10, Ex. 9 at 2.)

Sandoz's related implication, derived from a 2001 marketing document, that Allergan conceded "[n]o patent protection [was] available on combination product" is also wrong. (Dkt. 73 at ¶ 37 (brackets and additions by Sandoz).) The full statement from the document on which Sandoz relies, without Sandoz's additions and changes to that statement, is "No patent protection available on combination product – will receive three-year exclusivity in US." (Walsh Decl., Ex. L at AGN_COM00329702). In 2001, Allergan had not yet filed for or obtained any patents on Combigan®, but hoped for FDA approval quickly. Accordingly, the statement is one of fact—that, at the time, the product would only have a three-year exclusivity and no patent protection. The inferential leap Sandoz asks the Court to make—that this statement of fact in a marketing document was somehow a belief that no patent protection would be possible because the inventions were obvious—is gigantic and unwarranted.

Indeed, this last assertion by Sandoz demonstrates well the inequity Sandoz seeks to do in this case. The document it trumpets was featured prominently by a Sandoz attorney in closing argument in the very first trial. (Walsh Decl., Ex. G at 68:5-7.) The district court rejected the argument then, yet Sandoz now repeats it to this Court, knowing that it has already been rejected. That is inequity that should not be rewarded. Sandoz's counterclaims should be dismissed.

III. ARGUMENT

A. Sandoz's Infectious Inequitable Conduct Allegations are Prohibited Compulsory Counterclaims

As Sandoz admits (Dkt. 148 at 16), each of its counterclaims alleges "infectious" inequitable conduct—in other words, inequitable conduct allegedly committed during the prosecution of patents already litigated to finality, not during prosecution of the patents-in-suit. But, Sandoz's allegations as to those earlier-litigated patents were compulsory counterclaims in the parties' prior litigations over the very patents Sandoz now alleges are unenforceable.[2] Sandoz is barred from bringing its claims here by Fed. R. Civ. P. 13(a) and the doctrine of claim preclusion. *See Goodman Mfg. Co., LP v. Carrier Corp.*, No. 13-2014-SLR, 2014 WL 4954281, at *1-2 (D. Del. Sep. 23, 2014); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 931, 933-35 (D. Del. 1991).

Because Sandoz is barred from raising allegations of inequitable conduct regarding the earlier Combigan® patents, Sandoz cannot sustain its claims of infectious inequitable conduct. Infectious inequitable conduct, by its very nature, requires a finding of inequitable conduct during the prosecution of earlier patents in the same family. *Mosaid Techs. Inc. v. Samsung Elecs. Co*., 362 F. Supp. 2d 526, 555 (D.N.J. 2005) (concluding that because an earlier patent was not unenforceable due to inequitable conduct, the argument that the later related "patents are unenforceable due to 'infectious unenforceability' is perforce rejected."); *see also Correct Craft IP Holdings, LLC v. Malibu Boats, LLC*, No. 6:09-cv-813-28KRS, 2010 WL 598693, at *5 (M.D. Fla. Feb. 17, 2010) ("a court must 'find inequitable conduct sufficient to hold at least one patent unenforceable before considering whether to hold an entire group of related patents

[2] As explained in Allergan's Opening Brief, district courts have dismissed *Walker Process* claims as compulsory counterclaims based upon the same reasoning. (*See* Dkt. 112 at 20 n.10.)

unenforceable.'") (citing *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1259 (Fed. Cir. 2000)).

These cases are directly analogous. Just because Sandoz chose not to raise inequitable conduct in those litigations does not mean that it can raise inequitable conduct about those finally litigated patents as a basis for prevailing now. Were that the case, claim and issue preclusion would never apply to anything in a later litigation—all a litigant would have to do to avoid the preclusive effect of a prior judgment would be to simply remain silent. That is not the law.

As it does throughout its brief, Sandoz misconstrues Allergan's argument rather than addressing it head on. In response to Allergan's compulsory counterclaim argument, Sandoz first argues that the '453, '801 and '802 patents are asserted for the first time in the present litigation, and thus that its allegations cannot be barred. (Dkt. 148 at 15.) Sandoz's argument misses the mark. While it is true that the patents-in-suit here were not asserted in prior litigation, Sandoz's inequitable conduct allegations ***do not relate*** to conduct that occurred during the prosecution of the patents-in-suit.[3]

Instead, as Sandoz itself admits, Sandoz's "infectious" inequitable conduct allegations relate to conduct that occurred during the prosecution of other, earlier patents in the Combigan® patent family. (Dkt. 112 at 20; Dkt. 148 at 15-16.) Each of the acts or omissions that Sandoz uses to support its inequitable conduct allegations started with the prosecution of the '149 patent, the first patent in the family, and through the prosecution of the '425 patent. (Dkt. 73 at 89, 102, 120, 127, 134, 142-143, 150-151.) Thus, Sandoz is wrong that a cause of action did not exist when the earlier patents were litigated. Sandoz could have, and, if it wanted to preserve the argument, should have, raised inequitable conduct allegations related to the previously litigated

[3] All of the alleged bad acts, with the exception of the failure to submit Dr. Duh's report, occurred prior to the prosecution of the '453, '801 and '802 patents. Sandoz does not allege that the failure to submit Dr. Duh's report alone, amounts to inequitable conduct before the PTO.

patents when those patents were litigated. It chose not to, and must now live with the consequences of that decision.

Moreover, when the patents-in-suit were prosecuted, the Examiner had the information Sandoz alleges Allergan failed to disclose—e.g., the 507T study, FDA Medical Reviews, and the Alphagan Final Report. (Walsh Decl., Ex. M; Ex. N; Dkt. 148-3, Ex. 32 at 108-31.) Data from the 12T, 13T, 19T, 23T, and 24T studies were discussed in the FDA Medical Reviews and in the Eastern District of Texas' Finding of Facts and Conclusions of Law from the 2011 and 2016 trials, which were also before the Examiner. (*Id.*) Despite having the allegedly withheld information in front of her, the Examiner of the patents-in-suit allowed the claims. (Walsh Decl., Exs. O-Q.)

Dow Chem. Co. v. Metlon Corp., 281 F.2d 292, 297 (4th Cir. 1960), which Sandoz cites in support of its position, is inapposite. In *Dow*, the Fourth Circuit determined the defendant's counterclaim of invalidity and non-infringement was not a compulsory counterclaim to a previous lawsuit, where the underlying complaint alleging infringement was dismissed before the defendant even answered. Obviously, the procedural posture of *Dow Chemical* bears no resemblance to the history of this case. Here, a cause of action clearly existed in prior litigations where Allergan was seeking to enforce its '149, '976, '463, '258 and '425 patents—the very patents Sandoz now alleges were procured by inequitable conduct. *Allergan, Inc.*, 818 F. Supp. 2d. at 1031-1032; *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286 (Fed. Cir. 2013); Dkt. 112-3, Ex. A; *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x at 996. Sandoz even raised (but did not pursue) an unclean hands defense in the first litigation, an acknowledgment that it had the opportunity, and ability, to raise any equitable defenses during that litigation. (Walsh Decl., Ex. T at 10.) Sandoz's failure to raise inequitable conduct at that time bars it from doing so now.

Sandoz's next argument—that the facts it alleges on inequitable conduct on the prior patents somehow "did not exist" during the parties' prior litigations—is incredible. (Dkt. 148 at 2.) As detailed in Allergan's opening brief, Sandoz's inequitable conduct allegations here are merely a repackaging of its failed invalidity assertions from prior cases. (Dkt. 112 at 12.) For example, Allergan directly addressed Sandoz's allegations about the "closest prior art" in the previous litigations. The district court in the 2009-2013 litigation expressly agreed with Allegan's position that brimonidine TID was the closest prior art. *Allergan*, 818 F. Supp. 2d at 1024 ("[t]he comparisons made by Allergan are appropriate."). Similarly, the district court in the 2014-2017 litigation ultimately determined that "the efficacy and side effect results of Combigan® are unexpected compared to all prior art, including twice-daily adjunctive therapy, based properly on what was knowable through such prior art," and the Federal Circuit affirmed that finding. (Dkt. 112-3, Ex. A at ¶¶ 166-67); *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x at 994. Additionally, Sandoz not only presented and vigorously argued in the second litigation that the data presented in the 507T study was contrary to Allergan's unexpected results story, but also relied upon the results of that study, which were published in an article by Goñi that appears on the face of all the patents. (*See* Dkt. 148-2, Ex. 1-11.) The Texas district court rejected those arguments emphatically. (Dkt. 112-3, Ex. A at ¶¶ 155-60.) And the Alphagan® Final Report, all of the clinical studies on Combigan®, and FDA documentation, including the Medical Reviews, were previously listed on Sandoz's trial exhibit list in both litigations. (Walsh Decl. Ex. R at 2, 9, 10, 12, 13, 20-22, 34, 37, 41, 43; Ex. S at 3, 16-17.) Sandoz knew well of all of the facts allegedly underlying its inequitable conduct argument, but chose not to raise them.

Moreover, the vast majority of Sandoz's allegations are based on facts that are either in the file histories of the earlier Combigan® patents, (Dkt. 73, Counterclaim ¶ 16; *see also* Dkt.

112-1 at 1-2), which were certainly available to Sandoz in earlier litigations, or on Allergan's clinical trials, which Sandoz's own allegations show were all complete no later than 2007. (Dkt. 148 at 6.) Sandoz's assertion that the facts supporting its allegations were not previously available to it is simply not credible. Notably, after asserting that many of the facts supporting its inequitable conduct allegations "simply had not yet happened" at the time of the prior litigations (*id.* at 16), Sandoz fails to give a ***single*** example of such a fact.

Once Sandoz's allegations related to the previously litigated patents are stripped away, there is nothing left of Sandoz's inequitable conduct allegations against the '453, '801 and '802 patents. As a result, Sandoz's counterclaims 7-14 fail as a matter of law.

B. Sandoz's "Differing" Burdens Argument is Wrong

Each of Sandoz's allegations of inequitable conduct relies on Sandoz's assertion that if the Examiner had known about a particular piece of data or art, he or she would not have found that the claimed invention demonstrated unexpected results. (Dkt. 112 at 23-24.) But that argument, too, is merely a repackaging of Sandoz's failed invalidity positions from prior cases. Sandoz does not—because it cannot—dispute that two district courts and two panels of the Federal Circuit have made or affirmed a fact finding that Combigan® exhibits unexpected safety and efficacy, despite all of Sandoz's arguments to the contrary. *See Allergan, Inc.*, 726 F.3d at, 1293 ("The court found that a twice per day dosage regimen of Combigan® unexpectedly did not suffer from the afternoon trough issue. We agree with the court's finding that this result is unexpected."); *id.* at 1294 ("Finally, the court found that there were secondary considerations that support the finding of non-obviousness including long-felt need and unexpected results. We accept the district court's factual findings[.]"); *Allergan, Inc.*, 818 F. Supp. 2d. at 974; Dkt. 112-3, Ex. A at 61; *Allergan Sales, LLC*, 717 F. App'x at 994 ("Those efficacy limitations are not

disclosed by any prior art reference in the record" and are "not inherent in the administration of the ophthalmic composition").

Sandoz's assertion (Dkt. 148 at 20) that these court findings are not relevant because the PTO applies a different standard of review when evaluating patentability than the standard a court uses in reviewing validity is a red herring, because it has no bearing on the theory Sandoz pleads. Sandoz cites *Therasense* to raise two scenarios where, in theory, a claim could be valid, and yet unenforceable. The first is that the Patent Office uses a broader standard for claim construction that could potentially sweep in invalidating (and withheld) art, and the second is that the Patent Office uses a lower standard to show invalidity—preponderance rather than clear and convincing evidence. *See Therasense*, 649 F.3d at 1291-92; Dkt. 148 at 20. While those may be true statements of the law, they are irrelevant here. Sandoz identifies no broader claim construction that could impact the validity analysis, and no argument that the courts' findings in the prior cases suggest that unexpected results were "a close call" where the burden of proof on validity might make a difference. To illustrate, the Eastern District of Texas rejected out of hand Sandoz's contention that the 507T trial was relevant to unexpected results because of the short duration of that study, because of the patient population in that study, and because of the way the data was collected in that study, among other things. (Dkt. 112-3, Ex. A at ¶¶ 155-160.)

Moreover, Sandoz ignores that, in the prior litigations, it was Allergan's burden to show unexpected results. *Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015). Thus, in finding unexpected results, the prior courts were evaluating the very thing of which Sandoz complains—that, if only every single piece of evidence from litigation was before the Patent Office in the first instance, unexpected results would not have been found. That assertion by

Sandoz has already been found wanting. Four times.[4]

And here, not only have the courts repeatedly found that Combigan® exhibits unexpected efficacy and safety, (Dkt. 112-1 at 5-10), the examiner of the '453, '801, and '802 patents found the very same thing in allowing these patents. (Walsh Decl., Ex. O-Q.) And she did so even in the face of essentially all of the information allegedly withheld— e.g., the 507T study, FDA Medical Reviews (which included clinical study data), and the Alphagan Final Report.[5] (Walsh Decl., Ex. M, N; Dkt. 148-3, Ex. 32 at 113-31.) Because the PTO allowed the '453, '801 and '802 patents in light of the allegedly withheld information, Sandoz's argument that any of the patents in the Combigan® patent family would not have issued had those references been disclosed is not plausible. *See e.g., Arctic Cat, Inc. v. Polaris Indus. Inc.*, No. CIV. 13-3579 JRT/FLN, 2014 WL 5325361, at *23 (D. Minn. Oct. 20, 2014) (dismissing claim for inequitable conduct based on failure to disclose allegedly material reference where PTO subsequently issued a patent with identical specification and similar claims after reviewing previously withheld reference.) Sandoz's inequitable conduct counterclaims should be dismissed. *See, e.g., August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (affirming dismissal of inequitable conduct counterclaim where alleged prior art would not render asserted claims obvious in light of other cited prior art as a matter of law, and was therefore not material).

[4] Sandoz also ignores that its ultimate burden on inequitable conduct is "clear and convincing" evidence, the same burden as on invalidity in district court.

[5] Sandoz's allegations of the materiality of the alleged failure to submit David to the PTO are based on David's teachings regarding the long-term safety and efficacy of 0.2% brimonidine BID. (Dkt. 148 at 32-33.) These "teachings" of David, a review article, are in fact a recitation of the results of the Cantor and Melamed references that Allergan submitted to the PTO during the prosecution of at least the '425, '453, '801 and '802 patents. (Walsh Decl., Ex. U at AGN_COM00761650, -655; Ex. M at AGN_COM00765220, -227; Ex. N at AGN_COM00765924, -932; Dkt. 148-3, Ex. 32 at 116, 123.)

C. Sandoz Cannot Twist Allergan's Lawful Patent Actions into Antitrust Claims by Using the Sham Litigation "Series" Test or by Asserting Stale Inequitable Conduct Theories for an Untimely Walker Process Claim

Sandoz attempts to focus the Court's attention on the fact it that it spliced its allegations into three separate counts of monopolization: (1) sham litigation or a "series" of sham litigations, (2) alleged *Walker Process* fraud, and (3) a "pattern" of monopolistic conduct as part of an overall "scheme." (Dkt. 148 at 35.) But each claim is implausible individually and collectively.

First, Sandoz all but concedes that its sham litigation claim fails at the pleading stage if the "objectively baseless" test applies from *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.* ("*PRE*"), 508 U.S. 49 (1993). (*See* Dkt. 148 at 38 (Sandoz attempting to avoid "the fact that ***some of Allergan's claims may have been found to have some merit***" and stating that "it is conceivable that some claims may be successful.")) Notably, Sandoz does not dispute the uncontroverted record showing that Allergan ***won*** its first lawsuit and succeeded in the district court in its next consolidated lawsuit before being reversed on appeal. Sandoz also fails to address *PRE's* progeny where courts have rejected sham claims even when an innovator lost an infringement action, so long as it was "hard-fought and close." (Dkt. 112 at 37 (quoting *AstraZeneca AB v. Mylan Labs, Inc.*, No. 00-CV-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010); *see also id.* (citing *Synscort Inc. v. Innovative Routines Int'l Inc.*, No. 04-CV-3623 (WHW), 2008 WL 1925304, at *18 (D.N.J. Apr. 30, 2008) ("That this Court is not granting summary judgment . . . on all [] claims demonstrates that [plaintiff] had a reasonable belief that there was a chance that its claims would be upheld upon adjudication.").) Sandoz practically admits that its sham claim fails as a matter of law at the pleading stage under the *PRE* test.

Sandoz rests its entire argument on the "series test" and blatantly misrepresents that Allergan "ignores Third Circuit and other consistent precedent." (Dkt. 148 at 36.) But Allergan's opening brief clearly discussed the Third Circuit's test for a "series of legal

proceedings," including *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 181 (3d Cir. 2015), in the event the Court concluded it should apply here. Sandoz, however, fails to address that there are too few lawsuits to be a series. The Federal Circuit has refused to apply the series test to ***three*** lawsuits, and the Fourth Circuit has recognized that ***four*** actions may not be enough. (*See* Dkt. 112 at 34 n.13.) Here, there are two, or at most three, prior litigations. Thus, the *PRE* test should apply, and dismissal is warranted of Sandoz's sham litigation claim.

Moreover, Sandoz does not address the Third Circuit's reluctance to expand the series test to generic pharmaceutical litigation, which the Court of Appeals considered "particularly inapt" due to "the design and intent of Hatch-Waxman." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 157 (3d Cir. 2017). Sandoz does not and cannot deny that the regulatory scheme encourages patent infringement suits by innovators, and the Third Circuit is "not inclined to penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.'" *Id.* (citation omitted).

Regardless, even if the series test applies here, Sandoz never addresses how it can possibly state a plausible ***pattern*** of allegedly baseless actions given Allergan's litigation success at both the district court and Federal Circuit. Under the Third Circuit's test, a series is not a sham "[i]f ***more than an insignificant number*** of filings have objective merit." *Hanover*, 806 F.3d at 181. Allergan's successful track record in a small number of lawsuits is a far cry from the repetitive baseless litigations that courts have found could give rise to sham claims under the series test. *Compare Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354, 365 (4th Cir. 2013) (finding sham where ***one of fourteen*** proceedings succeeded); *with USS-POSCO Indus. v. Contra Costa Cont. Bldg. & Constr. Trades Council*, 31 F.3d 800 (9th Cir. 1994) (finding ***no sham*** where defendant won ***fifteen of twenty-nine***

lawsuits); *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1046 (9th Cir. 2009) (finding ***no sham*** where defendant won ***seven of fifteen*** lawsuits). Because Sandoz fails to allege that any prior Allergan lawsuit lacked merit, the Court should dismiss Sandoz's claim whether *PRE* or the series test applies.

As for Sandoz's second antitrust count, as described above in Section III.A, *Walker Process* claims are compulsory counterclaims that Sandoz was required to (and did not) assert in the prior litigations. They thus fail for the same reason as Sandoz's inequitable conduct claims.[6]

Finally, Sandoz's monopolization "scheme" boils down to nothing more than a pleading tactic to combine its deficient sham litigation and stale *Walker Process* counts. (Dkt. 73 at ¶ 73.) But Sandoz may "not use litigation conduct to support a claim of an overall scheme to monopolize ***if they cannot prove that the litigation was a sham***"—a proposition recognized by Sandoz's own cited authority. *Abbott Labs v. Teva Pharm USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006).[7] Therefore, to use Allergan's procurement of patents and subsequent lawsuits as the basis for a scheme, Sandoz must strip Allergan of its First Amendment *Noerr-Pennington* immunity. But Sandoz falls far short, and it cannot just combine these claims "as a subterfuge to avoid the stringent requirements of *Walker Process* or *Noerr* immunity." *Id.* at 430 n.7 (citation

[6] Moreover, half of Sandoz's alleged bases (1, 4, 5, and 8) for *Walker Process* fraud are time-barred because the allegedly fraudulent patents were procured ***over four years ago.*** Sandoz's citation to *Toledo Mack Sales & Service, Inc. v. Mack Trucks, Inc.*, 530 F.3d 204, 217 (3d Cir. 2008), for the unremarkable proposition that a "continuing violation" can toll the limitations period is inapposite because it did not involve a *Walker Process* claim. Allergan cited, and Sandoz ignores, authority finding that the statute of limitations for a *Walker Process* claim begins running when the allegedly fraudulent patent is procured. (*See* Dkt. 112 at 22 n.12.)

[7] *See also United Mine Works of Am. v. Pennington*, 381 U.S. 657, 670 (1965) (finding conduct protected from antitrust liability "not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act"); *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *17 (D.N.J. Aug. 28, 2009) ("[C]onduct protected by *Noerr-Pennington* immunity cannot be properly included within the scope of the monopolization scheme.").

omitted). Armed with no other conduct, Sandoz's scheme claim fails as a matter of law.

D. Sandoz's Conclusory Response Fails to Show Why this Court Should Not Bifurcate and Stay Burdensome, Complex, and Distinct Antitrust Claims

Sandoz's cursory, one-paragraph opposition to Allergan's alternative request to bifurcate and stay Sandoz's antitrust counterclaims fails to address Allergan's arguments. (*See* Dkt. 112 at 39-40.) Sandoz does not dispute that antitrust discovery is expensive, unique, and burdensome, or that injecting complex antitrust issues into a patent case would potentially confuse a jury and prejudice Allergan. And yet Sandoz claims ***no prejudice*** to itself from a stay. It will be nearly impossible to complete discovery of key antitrust-specific issues in what remains of fact discovery—another point Sandoz ignores. Moreover, Sandoz does not even address that its sham litigation and *Walker Process* claims could be entirely mooted (or substantially narrowed) depending on the outcome of the patent case.

Sandoz's response rests solely on two points: (1) "[c]ourts routinely decline to bifurcate claims that involve substantially overlapping issues;" and (2) there is "substantial potential overlap between Sandoz's patent and antitrust claims." (Dkt. 148 at 38.) Sandoz is wrong. First, far from being "routine", Sandoz cites only ***two*** cases to support its sweeping statement—an unpublished Federal Circuit decision issued 26 years ago, and a non-binding district court decision involving a funeral home's organ harvesting scheme. (*See id.*) Conversely, Allergan cited extensive precedent showing that courts routinely separate patent issues from antitrust counterclaims. (*See* Dkt. 112 at 38 (collecting cases).) Notably, Sandoz ignores that Judge Pisano bifurcated and stayed Sandoz's nearly identical antitrust counterclaims when it attempted this same tactic in a prior patent lawsuit. *See Sanofi-Aventis U.S. LLC. v. Sandoz, Inc.*, No. 07-CV-2762, 2009 WL 10678670 (D.N.J. Apr. 9, 2009). Sandoz's failure to address any of these authorities and its citation to two inapposite outliers show just how far Sandoz is stretching.

Finally, Sandoz's conclusory argument that the patent and antitrust claims in this case substantially overlap ignores that antitrust claims "require[e] discovery well beyond what is relevant to patent infringement and invalidity." *Orthophoenix, LLC v. Dfine, Inc.*, No. 12-1003, 2015 WL 1938702, at *1 (D. Del. Apr. 28, 2015). For example, the relevant market definition is a wholly unique antitrust concept that will be heavily litigated and require significant fact and expert discovery.[8] Additionally, Sandoz does not argue other antitrust elements (*e.g.*, monopoly power, antitrust injury) would overlap with complex patent issues hinging on the administration of Combigan®, prior clinical study results, or the alleged obviousness of Allergan's claimed inventions. Thus, Sandoz cannot credibly claim that deciding the patent issues in this case first would be an "unworkable and inefficient use of judicial resources." (Dkt. 148 at 38.)

IV. CONCLUSION

For the reasons above, Allergan respectfully requests that the Court dismiss Sandoz's inequitable conduct and antitrust counterclaims (counterclaims 7-18) and strike Sandoz's tenth affirmative defense, or in the alternative, bifurcate and stay Sandoz's antitrust counterclaims.

Dated: July 13, 2018

Respectfully submitted,

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[8] *See, e.g.*, Dkt. 112-1 at 39 n.17 (citing *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016), where the Third Circuit considered at length and ultimately rejected the narrow market definition of the "name-brand [product] and its generic counterpart." *Id.* at 437).

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